REMARKS

I. Status of the claims

Claims 4, 11, 12, 34, 37, 38, 41 - 47 are pending. Claim 12 remains withdrawn. Claims 11 and 42 have been amended to more clearly recite the method of the present invention. Support for the amendments to Claims 11 and 42 is found in Example 5 of the Specification and in paragraph 8 of the Declaration filed by the Inventor dated February 6, 2006. No new matter has been entered.

III. Rejection of claims under 35 USC 112

The rejection of claims 4, 11, 34, 37, 38, 41, under 35 USC 112, first paragraph, for lack of enablement is respectfully traversed.

The method of the present invention as recited in Independent Claim 11 as amended is for a method for detecting a hepatitis C virus (HCV) in a sample by obtaining a sample suitable for detection of virus by a probe monoclonal antibody, comprising the steps of:

(1) treating a virus-containing sample with a treatment solution containing (a) an anionic surfactant and (b) at least one agent selected from the group consisting of an amphoteric surfactant, a nonionic surfactant and a protein denaturant; such that the virus particle is disrupted, the virus antigen is exposed or released such that the virus antigen is denatured; and antibodies against the virus antigen, if present in the sample, are inactivated; and

(2) adding the treated sample to a probe monoclonal antibody that has been immobilized to a solid support, wherein the concentration of the surfactants used during the treatment step are diluted to an extent that said surfactants exhibit little or no denaturing properties to the probe monoclonal antibody, adding a reaction buffer to said treatment sample and probe monoclonal antibody and detecting the denatured virus antigen by immunoassay using the probe monoclonal antibody.

Independent Claim 42 recites the identical method for detection of Hepatitis B Virus (HBV).

The Examiner has stated in the Office Action that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with the claims of record. Applicant respectfully submits that the claims, as amended, accurately reflect the method of the present invention and now enable one of ordinary skill in the art to make/use the invention.

Applicants submit that the endogeneous antibodies, which must be inactivated, are exposed to SDS in the first step. In the first step, the antibody probe does not exist. The antibody probe exists only in the second step. Therefore, the endogenous antibodies and the antibody probe are not exposed to the same conditions. Attached as Exhibit A are diagrams illustrating the point that there are two (2) steps to the method of the present invention. Fig. 1 illustrates the treatment step and Fig. 2 illustrates the reaction step.

With regard to the Examiner's assertion that Table A of the February declaration does not comport with the concentrations disclosed in the specification, Applicant respectfully directs the Examiner's attention to Example 5, page 40 lines 225-29, wherein it is stated that 120 microL of the treated serum is to be utilized for the sample. On page 41, lines 4-6, it is stated that 120 microL of the reaction buffer is combined with the treated sample. Table A shows that the concentration of the SDS is 1.25%. This concentration is the FINAL concentration of the SDS, i.e., 100 microL of 5% SDS in the original treatment solution (page 40, line26), combined with 100 microL of serum would equal 200 microL of solution containing 2.5% SDS. Further combining 120 microL of a 2.5% SDS solution with 120 microL of a 0% SDS solution would result in 240 microL of a 1.25% SDS solution, as stated in Table A. Accordingly, Applicant submits that Table A and the specification conform with one another.

In addition, Applicant respectfully submits once again, that in light of the above discussion regarding the concentration of SDS in the treated serum prior to exposing same to the probe antibodies and the reaction buffer, there does not exist a sufficient

concentration of SDS to denature the probe antibodies. Therefore, the probe antibodies are able to bind to the denatured proteins of interest in the treated serum without being denatured themselves. In support of this, Applicants again refer to the following biochemical textbook, regarding binding of SDS and proteins. It is well known that about 1.4 g of SDS which is a strong modifier of proteins bonds to 1 g of proteins (New Biochemical Experimental Manuals, Proteins I, page 356; a printout of a web page from Sigma-Aldrich teaching Product No. L3771, was submitted previously). In the method of the present invention, the treated solution contains only 2.5% SDS when it is exposed to the probe antibodies. Upon addition of the reaction buffer, there exists only a 1.25% concentration of SDS. Thus, there does not exist a sufficient quantity of SDS to denature the probe antibodies.

It is submitted that the above facts are well known in the art, and a person with ordinary skill in the art can easily work the claimed method in accordance with the disclosure in the specification.

Furthermore, the effects of CHAPS, urea and Triton X-100 on the detection of HCV core antigen are shown in Example 4 of the specification (Figs. 2a and 4). As can be seen on page 6, lines 24-27 of the specification, the effects of the treatment step of the present invention are to disrupt the virions, fully expose the virus antigen and disrupt any antibodies already present in the serum. Step 2 requires the usage of any conventional buffer, with the understanding that the buffer to be used is suitable for the purpose at hand. The volume of the reaction buffer to be used is stated in the specification.

With regard to the Examiner's statement that "the specification gives no guidance as to what combination of components, other than those set forth above, would result in a treatment solution that would inactivate the endogenous antibodies present in step 1...but not inactivate the antibody probe subsequently used in the immunoassay", Applicants respectfully reiterate the arguments outlined above and further submits that the claim as amended clarifies the metes and bounds of the method of the present invention. Further, when said amended claim is read in conjunction with the Examples provided in the specification, there is no doubt as to how to practice the

method of the present invention.

Further, with regard to the Examiner's contention that the specification is not enabled for detection of HBV, Applicant submits that on page 9, lines 10 to 20:

> Furthermore, HCV which is an RNA virus, and HBV which is a DNA virus, are viruses which form virus particles having a structure comprising a structural protein encapsulating genomic RNA or DNA and a membrane surrounding it. In either embodiment, by using a treating method of the present invention, there is provided detection or determination of virus characterized by disrupting a virus particle of not only HCV or HBV but also a virus having similar a structure thereto, by fully exposing the virus antigen, and by detecting or determining said antigen.

More specifically, Example 14 in the specification describes a method for measurement of HBV core antigen.

The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). See also *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976).

Furthermore , the Federal Circuit in *In re Wands,* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) clearly stated that a rejection based on lack of enablement cannot be maintained when there is "considerable direction and guidance" in the specification; there was "a high level of skill in the art at the time the application was filed;" and "all of the methods needed to practice the invention were well known." 858 F.2d at 740, 8 USPQ2d at 1406, In that case, after considering all the factors related to the enablement issue, the court concluded that "it would not require undue experimentation to obtain antibodies needed to practice the claimed invention." *Id.*,8 USPQ2d at 1407.

Similarly, in the case at hand, there is considerable guidance in the specification, there is a high level of skill in the art and all of the methods ancillary to practicing the method of the present invention are well known. Therefore, Applicant respectfully submits that the specification of the present invention enables the claims as amended.

For all of the above reasons, claims 4, 11, 34, 37, 38, 41 - 47 are clearly enabled and therefore are patentable.

Reconsideration and allowance of claims 4, 11, 34, 37, 38, 41 - 47 is respectfully solicited.

III. Conclusion

In view of the foregoing amendment to the claims and remarks, it is respectfully submitted that the instant invention as defined in claims 4, 11, 34, 37, 38, 41 - 47 is in full compliance with all the statutory requirements of Title 35 USC, and, therefore, it is earnestly requested that the Examiner's rejection be withdrawn and that the pending claims be passed to issue.

Respectfully submitted
Attorney for Applicant,

Dated: August 21, 2007

By: _____
Charu Narang, Esq.
Registration No. 44,963

CUSTOMER NO. 01109

ANDERSON KILL & OLICK, P.C.
1251 Avenue of the Americas
New York, New York 10020-1182
(212) 278-1000

CERTIFICATE OF MAILING

I hereby certify that this *Amendment* is being deposited with the United States Postal Service via First Class Mail addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on August 21, 2007.

_____ (Typed or printed name of person mailing paper or fee)

_____ (Signature of person mailing paper or fee)

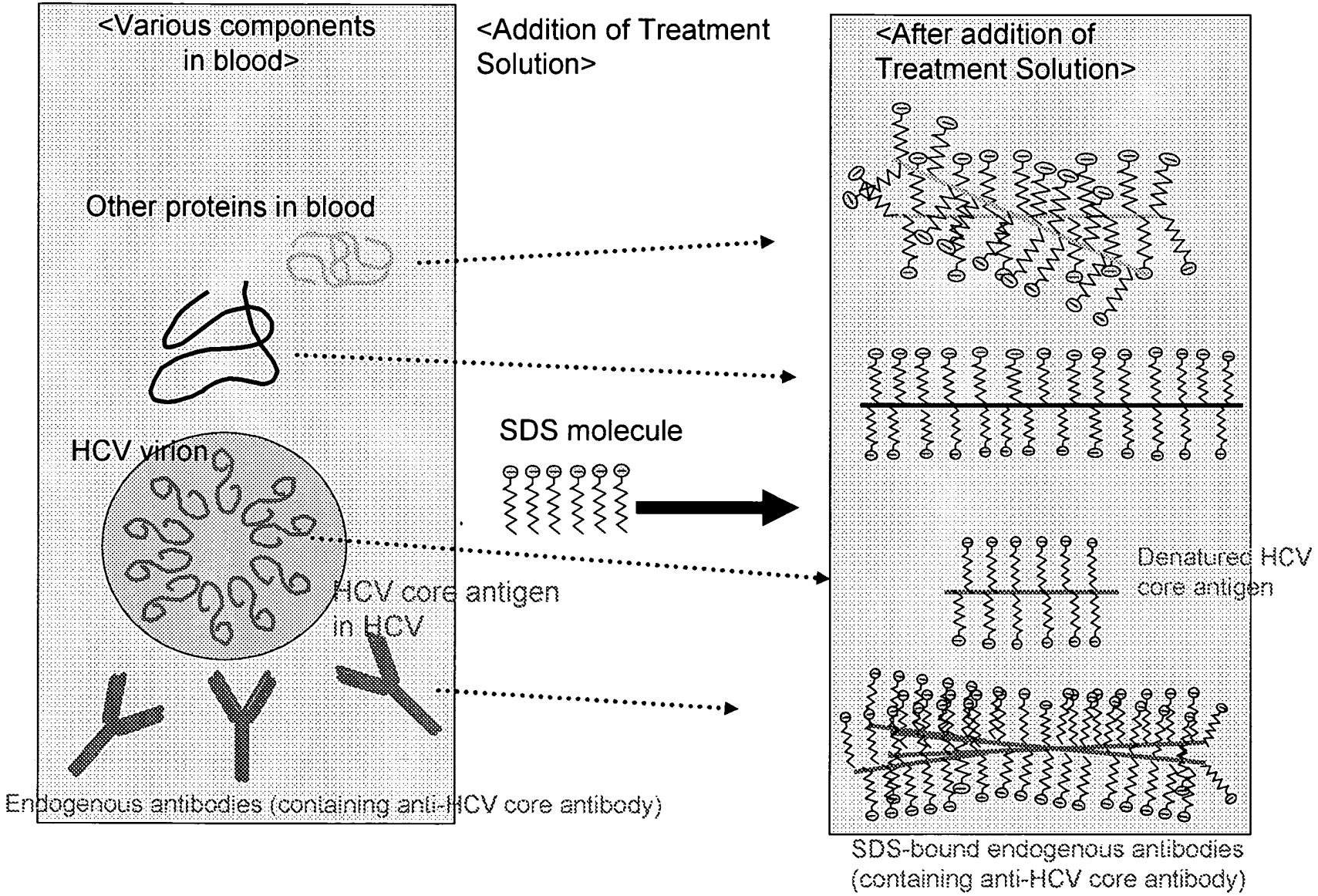

Fig. 1

1.4 g of SDS can bind to 1.0 g of protein in blood. After addition of Treatment Solution, SDS binds to various proteins containing HCV core antigen and various antibodies and denatures them.

SDS bound antibodies are destroyed the conformational structure and lost the ability to bind the antigen.

As protein concentration in blood is about 100 mg/mL, almost SDS molecule can bind to protein in blood.

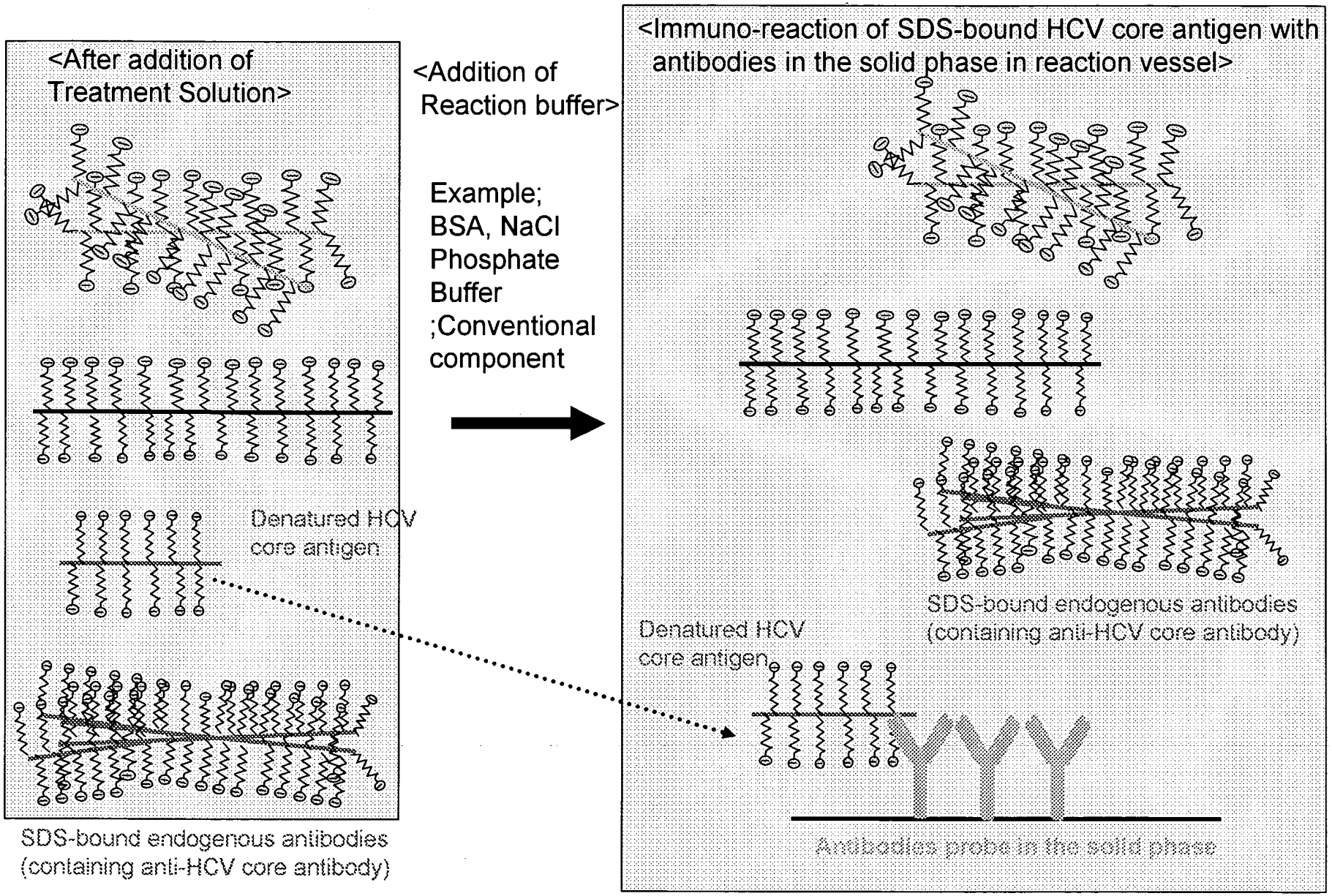

Fig. 2
SDS-bound endogenous antibodies can not bind to the antigen. Since there are hardly free SDS in reaction vessels, antibodies probe in the solid phase are not denatured and can bind to the antigen.